

RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects in Navy and Marine Corps Research

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human.research@med.navy.mil

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Comment

Surface Warfare, HRPP

Our summer issue, released in July, reported a decisive event for the DON HRPP and the Line Navy: the signing, by VADM W. H. Hilarides, Commander, Naval Sea Systems Command (NAVSEA) of NAVSEA Headquarters Instruction 3900.12, standing up the Command's HRPP.

NAVSEA, the largest of the SYSCOMs, employs some 60,000 government civilians, military personnel, and contractors at 33 facilities in 16 states, who manage more than 160 acquisition programs including new ship and submarine construction, development of hull, mechanical & electrical systems, and many other shipboard systems. The new Instruction also covers NAVSEA's affiliated Program Executive Offices, which manage the integration of sensors, weapons, as well as new command and control, communications, computer, and surveillance and intelligence systems for such complex missions as mine countermeasures, anti-submarine and anti-surface warfare, ship self-defense, among others.

NAVSEA HQ, in Washington, D.C., encompasses the Naval Surface Warfare Center (NSWC) and Naval Undersea Warfare Center (NUWC), administrative parents of several facilities which hold DON HRPP-issued Assurances: NSWC's Dahlgren, Va., Carderock, Md., and

Panama City, Fla., laboratories, and NUWC's site at Newport, R.I. The Navy Experimental Diving Unit (NEDU), in Panama City, also reports to NAVSEA HQ.

The bottom line for research at all the NSWC labs is surface warfare—with which NUWC and NEDU, while not focused directly on the surface mission, share important interfaces.

DON HRPP's oversight and monitoring role at NAVSEA HQ and at the surface labs serves a huge mission, because surface warfare historically has represented the Navy's fundamental character. Navies are—and always have been, in a word—ships.

This unremarkable truth resonates even more powerfully today, as the surface warfare force is configuring itself for missions and challenges radically unlike those of even the recent past.

"Surface warfare" now means ballistic-missile defense; support for joint-service special operations; precision launch of Tomahawk cruise missiles at land targets; and coordination and control for Marine Expeditionary Unit landings, which include long-range transit to theater of personnel and materiel and high-speed, just-in-time movement of logistics for the landing force.

The complexity and sophistication

of the technologies, tactics, and personnel skill sets needed for these newly urgent requirements demand the research carried out by NAVSEA HQ and its labs.

The NAVSEA research community is engaged deeply with human subjects because sailors and Marines are the fundamental components of surface and undersea warfare. Ships now sail with far smaller crews, but personnel must be more capable and versatile than ever for navigation, ship operations, weapons handling, machinery control, system and data management, and countless other assignments.

The surface warriors' competence evolves from research. It emerges also from daily cooperation and collaboration with DON HRPP staffers, who support the research that supports the fleet.

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**CDR Deniston Interim
DON HRPP Director**

**Interview: CAPT Mike Smith, CO,
Stuart Koch, Tech. Director,
NSWC Dahlgren Division**

HRPP for the Surface Force

DON HRPP Training Resources

*Director's Notes***HRPP's Continuing Contribution for Surface RDT&E***By CDR William Deniston*

The decisive role played by the Navy's surface warfare laboratories, at Dahlgren, Va., Carderock, Md., and Panama City, Fla., in developing warfighting systems and technologies is reflected in the prominence of DON HRPP's oversight at those Commands. That's because, as shipbuilding and ship-systems development is fundamental to Navy operations, so too is the role of research with human subjects in the evolution of ships and systems.

Our aim in this issue is to provide DON HRPP professionals some helpful background on the Navy's surface force. As described by CAPT Mike Smith and Mr. Stuart Koch, Commanding Officer and Technical Director, respectively, at NWSC Dahlgren, starting on page 3, the Navy is pursuing—as budgets permit—new initiatives for systems engineering and systems integration to enhance the capabilities of the surface force.

Those efforts reflect a new strategic posture of “pivot to the Pacific” and crisis readiness in the volatile Central Command area of operations in the Middle East and Southwest Asia. That means, once again, reliance on the power and mobility of the surface Navy.

Naval Surface Warfare Center's Dahlgren Division, a critical center for research with human

subjects, acts as combat systems engineering and integration (CSE&I) agent for the Aegis combat system for Ticonderoga-class cruisers and Arleigh Burke-class destroyers, and similar systems for Nimitz- and Ford-class aircraft carriers and the fleet's newest amphibious assault ships.

At Dahlgren and elsewhere, the CSE&I mission for sensors, weapons, and computers now has evolved into high-level “system-of-systems” engineering that depends heavily on human-systems engineering, a subset of research involving human subjects—the world of DON HRPP.

As the relationship between systems engineering and human subjects research became well-understood at the surface warfare labs, systems engineers have come to recognize that close collaboration with the DON HRPP's compliance specialists is a non-negotiable component of the effectiveness in design of advanced ship systems.

Such collaborations reinforce DON HRPP's credibility with the surface community, and underline our effectiveness in ensuring that human subjects research for surface-warfare programs produces critical capabilities for warfighters, as well as reaffirming the topmost priority of protecting subjects who support the work.

Deniston Interim DON HRPP Director

Former DON HRPP Deputy Director CDR William Deniston is serving as Interim Director while CAPT Alan Nordholm is on convalescent leave.

Deniston, a native of Carbondale, Ill., was commissioned in December 1996 and earned his Ph.D. in experimental psychology at Southern Illinois University in 1997. He joined the Naval Health Research Center in 1997, and was appointed as program manager in NHRC's Field Medical Technologies department in 2000. He then served at Space and Naval Warfare Systems Center as co-lead for Command performance improvement.

Deniston reported to the Office of Naval Research in October 2004, initially as Deputy Director of the Neural, Cognitive, and Social S&T Division.

In September 2005 he was named Deputy Director of ONR's new Research Protections Division. He became Deputy, DON HRPP in September 2007. From January 2010 to Dec 2012 he served as Assistant for Command Climate Evaluation at the Office of the Naval Inspector General. In January 2013 he was named Program Manager, Deployment Mental Health Research in the Wounded, Ill & Injured program, Bureau of Medicine and Surgery.

Interview, Naval Surface Warfare Center, Dahlgren Division**“We’re the Technical Experts on Combat Systems”**

CAPT Michael Smith assumed command at NSWCDD in July 2010 after serving as Deputy Program Manager for the Zumwalt-class (DDG-1000) program. He enlisted in the Navy in 1976. After leaving the Navy he earned his B.S. in Environmental Resource Engineering at Humboldt State University before receiving his Navy commission as an Engineering Duty Officer; later he also earned a B.S. in Naval Engineering and M.S. in Mechanical Engineering at MIT. CAPT Smith served aboard the destroyer Robison (DDG-12) as Main Engines Officer, Main Propulsion Assistant and Anti-Submarine Warfare Officer. He has served as Surface Ship Structures Officer, Canada Department of National Defence; Technical Director for PEO Ships-Fleet; Mission Systems Integration Officer for the DD(X) program; and Littoral Combat Ship Requirements Officer.

Mr. Stuart Koch was selected as a Senior Scientific Technical Manager in September 2004 after serving as the first NSWCDD Technical Operations Manager. Mr. Koch earned his B.S. in Electrical Engineering from Penn State University before joining NSWC as a radar systems engineer. Mr. Koch has held leadership positions for the NSWCDD Integrated Warfare Systems Department, and served as Head, NSWCDD Radar Systems Branch and Head of the Space and Ballistic Missile Defense Division. From 1998 to 2000, Mr. Koch was Senior Technical Advisor to the Director, Surface Warfare Division, Office of the Chief of Naval Operations (OPNAV). Mr. Koch holds an M.S. in Public Administration from Indiana University.

Please provide some perspective on NSWCDD’s mission in support of Navy combat systems development.



CAPT Michael Smith

SMITH: Dahlgren conducts research, development, test, and evaluation of combat systems for Navy ships and submarines. We’re probably more involved in the development than anything else—we certify the combat systems, make sure they’re properly integrated, and deliver them to the fleet.

KOCH: The combat systems role is probably right down the center of our mission statement. So while there’s a pretty broad spectrum of customers and types of work we do, the vast majority of it supports some aspect of the technology or the various components that comprise the combat system—the development, integration, and support for the fielding of those systems.

I understand Dahlgren has been overseeing the introduction of commercially developed technology for Aegis [the Aegis combat system in

use aboard Ticonderoga-class cruisers and Arleigh Burke-class destroyers].

KOCH: Yes—the continual morphing of the roles for Aegis is fairly recent, and we’re back to assuming greater control on the government side of the integration responsibility.

Are you focused on the latest Aegis baseline, advanced capability build 12 (ACB-12) for ballistic missile defense (BMD) right now?

SMITH: Yes, very much so. Previous to these most recent builds, a ship could only conduct either anti-air warfare or BMD. Now we’re bringing them in so the ships can do both missions simultaneously.

Is that work going on at Dahlgren right now?

SMITH: It’s taking place at various sites, depending on what the needs are. Much of it is going on here. There are certain tests that we can do only at Wallops [Surface Combat Systems Center, Wallops Island, Va.], because of the configuration of the combat systems there. They have more equipment out there that is ship-representative, including radars that can radiate over water. So we do tests out there that are linked to the systems back here, so it’s actually one big testing network.

(Continued on page 4)

NSWC Dahlgren Division

“We Do a Lot of Interfacing with the Fleet”

(Continued from page 3)

You’re monitoring and observing the testing on-site at Dahlgren while they’re being conducted at Wallops?

SMITH: Here and at the Combat Direction Systems Activity at Dahlgren, and at Wallops itself. The testing is all networked together.

What is the status of ACB-12?

SMITH: ACB-12 is in the throes of getting fielded and certified. ACB-16 is under development.

Is that work a partnership between Dahlgren and [Aegis prime contractor] Lockheed Martin?

SMITH: Yes—elements of the code are written by



Stuart Koch

Lockheed Martin and tested and delivered to the Navy, where some pieces are integrated together and tested at a higher level, and ultimately those get tested and certified by the Navy.

Is Dahlgren looking at upgrades to the non-Aegis combat system, the Ship Self-Defense System [SSDS Mk 2, installed aboard aircraft

carriers and large-deck amphibious ships]?

SMITH: Yes, in fact, upgrades to SSDS are going on in very much the same vein as for Aegis.

They’re using the ACB process as well, which is upgrading the system to a more commercial off-the-shelf -based computer architecture, more open architecture operating systems, and taking advantage of a lot of the same benefits that it brings to Aegis.

Are you looking at the DDG-1000 guns or other shipboard weapons?

SMITH: The new Advanced Gun System [AGS] six-inch gun is for the DDG-1000 [Zumwalt-class destroyer]. We will certify the DDG-1000 combat system when it is ready to be delivered to the fleet.

We do a lot of testing of guns here—the fuzing and fire control system of guns. We are not testing the six-inch gun because the range of that gun far exceeds the range that we would have to shoot here.

A lot of that testing gets done at White Sands Missile Range (N.M.) and Dugway Proving Ground, Utah, because they each have a range long enough to facilitate the Long-Range Land-Attack Projectile (LRLAP) rocket-thrown projectile. The LRLAP is actually part of the AGS. There is a program—I don’t think it’s a program of record yet—to make a LRLAP in a smaller caliber, say a five-inch, that could be shot out of an already-fielded shipboard five-inch gun.

How does NSWCDD coordinate with contractors and operators in transitioning technology, once it’s certified for the fleet?

SMITH: Most of the people who do the delivery to the ships are civilian government employees; a few are officers and senior enlisted who go with those teams and interface with the fleet. When they deliver a computer program to a ship, they’ll not only do the installation, but also testing to ensure the crew is familiar with the new test load. The crew will already have received training, and if there are any differences between what they’ve learned and what’s actually being delivered, they’ll go over those differences.

We do a lot of interfacing with the fleet well before we get to a certified combat system. We’ll work with the fleet early on in the generation of requirements.

In the testing we’ll even bring in fleet [operators] to see if there are any fleet issues involved with its use and maintenance, so that those things can get fixed well prior to the certification.

What is Dahlgren’s role in helping to support the Office of the Chief of Naval Operations [OPNAV] in developing requirements for combat systems capabilities?

KOCH: We’re the technical experts on combat systems, so we work both with OPNAV and the program offices to get them the technical expertise to define those requirements to determine what the combat system has to do, and what’s the best approach to doing that.

(Continued on page 5)

NSWC Dahlgren Division

Interoperability of Combat Systems ... Is a High Priority”

(Continued from page 4)

What are some of the most critical challenges you’re looking at right now in terms of combat systems integration for the surface force?

KOCH: One of the major ones is helping the program offices reduce the number of different computer program baselines that are out in the fleet right now. There are still a large number and still a lot of cost associated with maintaining and tracking all those various systems. So trying to narrow down to as few as really makes sense in a cost-effective manner is one of the big drivers right now.

USN/M. FORBES



Big-deck amphibious assault ships are fitted with the ship self-defense system (SSDS). Shown here: the amphib Wasp (LHD-1) underway in the Atlantic.

Another one, which has been on the radar screen for a while, is the interoperability of the various combat systems and units. So that’s a high priority, as the number of units stays stable and the number of missions keeps going up. You wind up with different mixes of ship classes together than you might have historically, so we need to understand and make them as able as possible to effectively interoperate together.

Can you give us some insight into Dahlgren’s work anticipating the development of some of the systems that will go aboard the Flight III DDGs [next-generation Arleigh Burke-class destroyer]?

SMITH: I think one of the newest architectures that

will go on that ship is the advanced air and missile defense radar [AMDR]. We’re very much working with the program offices in Washington, D.C., on the development of that particular radar.

What is your role for the AMDR?

SMITH: We’ve been involved in the generation of the requirements all the way through to the review of various architectures. Dahlgren certainly has been involved with the radar piece itself, the AMDR, coupled with the Aegis combat system.

KOCH: We’re certainly involved with the program office to identify various capabilities that would meet the requirements for the Flight III destroyers—making the tradeoffs of the various technologies and capabilities.

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This photo shows the first full-energy shot by the Navy’s electromagnetic railgun prototype launcher at NSWC Dahlgren.

In terms of systems like AMDR and future shipboard weapons like the electronic railgun and shipboard lasers, is Dahlgren engaged in working on power architectures to generate the power needed to support future weapons?

SMITH: Yes, absolutely. The power generation is part of the mission of the NSWC Carderock Division, mostly in Philadelphia.

We’ve been working with them on the generation of power, both at the various voltage levels and power requirements for those particular radars.

Training and Education

New DON HRPP Presentations Available for Continuing Education

By Sandy Sanford

DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," released in October 2011, requires education and training for all DoD personnel involved in the conduct, review, or approval of research involving human subjects.

The DoD instruction also directs the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) to "establish a framework for educational training requirements for DoD personnel in key roles."

In August 2012 ASD(R&E) issued a memorandum on the Minimum Education Requirements for DoD Personnel Involved in Human Research Protection (*Research Protections Update*, Fall 2012).

Available Presentations:

DoD Personnel as Subjects; Modifications to Secure Approval; Exempt and Expedited; Policy and Regulations; PI Responsibilities; Consent Readability; IRB Review; IRB Minutes; Research Involving Human Subjects; Transfer of PI.

One of DON HRPP's key missions is to develop training and continuing education programs in human research ethics for all HRPP staff members at DON Commands that conduct research with human subjects.

As part of that initiative, DON HRPP has developed a library of presentations to assist the

research community at Navy and Marine Corps Commands in conducting research that complies with DoD and DON policies on ethical treatment of subjects. Many have been used for educational sessions during DON HRPP Command site inspections and assist visits; others have been developed specifically for use by Commands themselves.

All are suitable for use for local continuing education.

The presentations address a wide range of human research protections problems and challenges, including such areas as informed consent; designating research as exempt and expedited; various topics associated with IRB processes; principal investigators; among others.

The presentations have proven especially helpful for continuing education by IRBs, which can use them during meetings to help members stay abreast of evolving ethical and regulatory issues.

They also are effective and informative tools for orientation and training for new IRB members.

The list of presentations currently available is posted on the DON HRPP web site under "Education & Training"

(<http://www.med.navy.mil/bumed/humanresearch/Pages/EducationTraining.aspx>).

Be sure to check the DON HRPP website for new postings as we continue to add more presentations.

Sandy Sanford, RN, MSN, CIP is Education Specialist for the DON HRPP. Her first research position was as research nurse for the Department of Emergency Medicine at The George Washington University, responsible for coordination of clinical research. She then served as Director of Education and Certification at the Association of Clinical Research Professionals, and as Director of Human Research Protection Accreditation at the National Committee for Quality Assurance, where she developed accreditation standards for human subjects research. Before joining DON HRPP she was Director for the Office of Research Subject Protections at George Mason University.

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